JUL 24 2009

# 510(k) SUMMARY

K091454

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K091454

**Submitted By:** Medtox Diagnostics, Inc.
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**Date Prepared:** May 12, 2009

**Proprietary Name:** PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System

**Common Name:** Colorimeter, Drugs of Abuse Test System

**Classification Names:**
The applicant test system regulatory classification is Class II; the Classification Panel is Clinical Toxicology (91) and Clinical Chemistry (75). Regulatory information applicable to the test system is provided below:

| CFR Section | Product Code |
|---|---|
| 862.2300, Colorimeter, Photometer, Spectrophotometer for Clinical Use | JJQ |
| 862.3100, Amphetamine Test System | DKZ |
| 862.3150, Barbiturate Test System | DIS |
| 862.3170, Benzodiazepine Test System | JXM |
| 862.3250, Cocaine and cocaine metabolite Test System | DIO |
| 862.3620, Methadone Test System | DJR |
| 862.3610, Methamphetamine Test System | DJC |
| 862.3650, Opiate Test System | DJG |
| 862.3650, Opiates Test System (Oxycodone) | DJG |
| 862.3100, Amphetamine Test System (Phencyclidine) | LCM |
| 862.3700, Propoxyphene Test System | JXN |
| 862.3870, Cannabinoid Test System | LDJ |
| 862.3910, Tricyclic Anti-depressant Drugs Test System | LFG |

**Predicate Devices:** PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System (K080635); MEDTOX® OXYCODONE (K060351); VERDICT®-II PROPOXYPHENE (K020387); PROFILE® -ER (K002331)

**Description of the Device**
The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The MEDTOX*Scan*® Reader is an instrument used as an aid in determining the presence or absence of a colored line associated with the PROFILE®-V MEDTOX*Scan*® one-step drugs of abuse qualitative screening immunoassays for the detection of one or more of the following in human urine: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone,

Phencyclidine, Propoxyphene, THC (Cannabinoids) and Tricyclic Antidepressants or their metabolites. All analytes were previously cleared (K080635) except for the oxycodone, propoxyphene, and tricyclic anti-depressant analytes.

The MEDTOX*Scan*® reader scans the device and utilizes a contact imaging sensor (CIS) to capture relative line intensities. Software algorithms and barcodes are used to identify the type of device to be read, the analyte(s) associated with the device and whether the presence or absence of a line is associated with a negative or positive result. The results of the scans are displayed on the MEDTOX*Scan*® screen or optionally can be printed.

**Intended Use**

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The PROFILE®-V MEDTOX*Scan*® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids), and Tricyclic Antidepressants or their metabolites. The PROFILE®-V MEDTOX*Scan*® Test Devices can only be used with the MEDTOX*Scan*® Reader. The MEDTOX*Scan*® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOX*Scan*® Test Device. PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is for *in vitro* diagnostic use and is intended for prescription use only. It is not intended for use in point-of-care settings.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

| | | | |
|---|---|---|---|
| AMP Amphetamine (d-Amphetamine) | 500 ng/mL | OPI Opiates (Morphine) | 100 ng/mL |
| BAR Barbiturates (Butalbital) | 200 ng/mL | OXY Oxycodone (Oxycodone) | 100 ng/mL |
| BZO Benzodiazepines (Nordiazepam) | 150 ng/mL | PCP Phencyclidine (Phencyclidine) | 25 ng/mL |
| COC Cocaine (Benzoylecgonine) | 150 ng/mL | PPX Propoxyphene (Norpropoxyphene) | 300 ng/mL |
| MAMP Methamphetamine (d-Methamphetamine) | 500 ng/mL | THC Cannabinoids (11-nor-9-carboxy-△9-THC) | 50 ng/mL |
| MTD Methadone (Methadone) | 200 ng/mL | TCA Tricyclic Antidepressants (Desipramine) | 300 ng/mL |

Configurations of the PROFILE®-V MEDTOX*Scan*® Test Devices may consist of any combination of the above listed and previously cleared drug. Refer to specific product labeling for the combination of drug tests included on that test device.

THE PROFILE®-V MEDTOX*Scan*® DRUGS OF ABUSE TEST SYSTEM PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY / TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

The MEDTOX*Scan*® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOX*Scan*® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOX*Scan*® Reader and a contaminated contact imaging sensor (CIS), and to verify that the CIS cleaning procedure using the MEDTOX*Scan*® Cleaning Cassette effectively removed any contamination.

**Discussion of Technological Characteristics:**

**a. Similarities and differences to predicate devices**

Both the applicant and the predicate test systems are used to detect the presence of drugs of abuse and their metabolites in human urine. In both systems, a urine sample is added to the test device and allowed to react for a specified period of time, after which an instrument is used to read the test device and interpret and display the test result. Both the applicant and predicate test devices are rapid single use disposable devices that use immunochromatographic lateral flow technology. Both the applicant and predicate test devices utilize gold-conjugated reagents to generate the reddish-purple test and controls lines, which are read by the instrument.

Overall characteristics of the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System and the predicate devices are summarized in Tables below:

Predicate Test System – K080635

| **Similarities** | | |
|---|---|---|
| Item | Additional or Expanded Indications | Predicate, K080635 |
| Intended Use | Determines qualitative positive or negative result from drug of abuse immunoassay screens. | Same |
| System Procedure | Sample is added to a single use test cassette, which is then read by instrument. Instrument is designed to read multiple single use test cassettes, one at a time. | Same |
| Measurement Method | Scans the single-use test cassette to detect a signal. | Same |
| Output | Outputs "positive," "negative," and "invalid" test results on paper printout or LCD screen; stores and uploads results. | Same |

| **Differences** | | |
|---|---|---|
| Item | Additional or Expanded Indications | Predicate, K080635 |
| Analytes | Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids), and Tricyclic Antidepressants | Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and THC (Cannabinoids), |
| Factory Calibration | A five point threshold calibration method is used. | A single point + 3 SD threshold calibration is used. |
| Timing Modes | Clinical samples are run in instrument-timed mode only | Clinical samples are run in either instrument-timed or user-timed modes |

*Table 1. Comparison of Similarities and Differences for the* PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System *and predicate instrument system.*

Predicate Devices – K060351 (OXY); K020387 (PPX); K002331 (TCA)

| Similarities | | |
|---|---|---|
| Item | Additional or Expanded Indications | Predicates: K060351 (OXY); K020387 (PPX); K002331 (TCA) |
| Intended Use | Determines qualitative positive or negative result from drug of abuse immunoassay screens. | Same |
| Analytes | Additional Analytes: Oxycodone, Propoxyphene, and Tricyclic Antidepressants | Same or Included |
| Cutoffs | Oxycodone at 100ng/mL, Propoxyphene at 300ng/mL, and Tricyclic Antidepressants at 300ng/mL | Same |

| Differences | | |
|---|---|---|
| Item | Additional or Expanded Indications | Predicates: K060351 (OXY); K020387 (PPX); K002331 (TCA) |
| System Procedure | Sample is added to a single use test cassette, which is then read by instrument. Instrument is designed to read multiple single use test cassettes, one at a time. | Sample is added to a single use test cassette, which is then read visually by the operator. |
| Measurement Method | Scans the single-use test cassette to detect a signal and compares to instruments calibrate threshold. | Operator visually determines the presence or absence of a line at the test position. |
| Output | Outputs "positive," "negative," and "invalid" test results on paper printout or LCD screen; stores and uploads results. | Operator visually determines whether test is "positive," "negative," or "invalid" and records results manually. |
| Timing Modes | Instrument internally times test strip development and scans test cassette at appropriate time. | Operator manually times test development and visually reads test cassette at appropriate time. |

*Table 2. Comparison of Similarities and Differences for the* PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System *and predicate visual devices.*

**Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:**

See K080635 for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Phencyclidine, and THC (Cannabinoids), Performance studies have been conducted for the addition of Oxycodone, Propoxyphene, and Tricyclic Antidepressants through Medtox's internal Design Control process. Performance characteristics are exactly the same and data are on file at Medtox.

The following laboratory performance studies were conducted to determine the substantial equivalence of the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System to the predicate:

- Performance of the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System around the specific cutoff for Oxycodone, Propoxyphene, and TCA was evaluated by testing standard drug solutions diluted in drug-free urine in triplicate on 5 different intervals by 3 in-house operators using different readers (45 determinations for each level). Drug free urine was also tested on each interval. The results were interpreted at ten minutes by the MEDTOX*Scan*® Reader and are summarized for each drug in Table 2 below:

**Table 2. Sensitivity/Precision/Distribution of Random Error**

| Sample Concentration (ng/mL) | % of Cutoff | Number of Observations | # Neg | # Pos |
|---|---|---|---|---|
| **OXY (100)** | | | | |
| 0 | Neg | 45 | 45 | 0 |
| 25 | 25% | 45 | 45 | 0 |
| 50 | 50% | 45 | 44 | 1 |
| 75 | 75% | 45 | 19 | 26 |
| 125 | 125% | 45 | 0 | 45 |
| 150 | 150% | 45 | 0 | 45 |
| **PPX (300)** | | | | |
| 0 | Neg | 45 | 45 | 0 |
| 150 | 50% | 45 | 45 | 0 |
| 225 | 75% | 45 | 31 | 14 |
| 375 | 125% | 45 | 2 | 43 |
| 450 | 150% | 45 | 0 | 45 |
| **TCA (300)** | | | | |
| 0 | Neg | 45 | 45 | 0 |
| 150 | 50% | 45 | 45 | 0 |
| 225 | 75% | 45 | 9 | 36 |
| 375 | 125% | 45 | 0 | 45 |
| 450 | 150% | 45 | 0 | 45 |

- Other Technical Performance Documentation for the MEDTOX*Scan*® include:

  - Influence of Temperature
  - Influence of Humidity
  - Factory Calibration
  - Electrical and EMC Testing
  - Validation and stability of QC Control Cassette
  - Validation and stability of Cleaning Cassette

- Analytical specificity (cross reactivity and interference) data are summarized below.

**Related Compounds and Cross Reactants**

The metabolites and reacting compounds shown in Table 3 below were evaluated on the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System for interference or cross reactivity with Oxycodone, Propoxyphene, and Tricyclic Antidepressent (TCA). Reference standards for the various metabolites and compounds were prepared in negative urine samples. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay. Compounds that reacted with the test are listed first, and related compounds that did not react with the highest concentration tested are listed second as Negative at 100,000 ng/mL. The "% Cross-Reactive" values were calculated from the cut-off level for the calibrator used for each test (approximate 50% positive rate) divided by the lowest reported level found to react in the same test (greater than 66% positive rate).

**Table 3. Related Compounds and Cross Reactants in the MEDTOX*Scan*® Drugs of Abuse Test System**

| **Oxycodone (OXY) *(Oxycodone) 100 ng/mL*** | | |
|---|---|---|
| **Compound** | **Result** | **% Cross-Reactive** |
| Codeine | Positive at 5000 ng/mL | 2% |
| Dihydrocodeine | Positive at 25,000 ng/mL | <1% |
| Ethylmorphine | Positive at 7,500 ng/mL | 1% |
| Hydrocodone | Positive at 50,000 ng/mL | <1% |
| Hydromorphone | Positive at 50,000 ng/mL | <1% |
| Morphine | Positive at 25,000 ng/mL | <1% |
| Morphine 6-β-D-Glucuronide | Positive at 100,000 ng/mL | <1% |
| Naloxone | Positive at 25,000 ng/mL | <1% |
| Norcodeine | Positive at 100,000 ng/mL | <1% |
| Oxymorphone | Positive at 250 ng/mL | 40% |
| Naltrexone | Positive at 50,000 ng/mL | <1% |
| | | |
| Apomorphine | Negative at 100,000 ng/mL | None Detected |
| Diacetylmorphine | Negative at 100,000 ng/mL | None Detected |
| Levorphanol | Negative at 100,000 ng/mL | None Detected |
| 6-Monoacetylmorphine | Negative at 100,000 ng/mL | None Detected |
| Morphine 3-β-D-Glucuronide | Negative at 100,000 ng/mL | None Detected |
| Nalorphine | Negative at 100,000 ng/mL | None Detected |
| Thebaine | Negative at 100,000 ng/mL | None Detected |
| | | |
| **Propoxyphene-(PPX) *(Norpropoxyphene) 300 ng/mL*** | | |
| **Compound** | **Result** | **% Cross-Reactive** |
| Propoxyphene | Positive at 50 ng/mL | 600% |
| | | |
| **Tricyclic Antidepressant (TCA) *(Desipramine) 300 ng/mL*** | | |
| **Compound** | **Result** | **% Cross-Reactive** |
| Amitriptyline | Positive at 500 ng/mL | 60% |
| Clozapine | Positive at 7,500 ng/mL | 4% |
| Cyclobenzaprine | Positive at 20,000 ng/mL | 2% |
| Doxepin | Positive at 1,300 ng/mL | 23% |
| Imipramine | Positive at 250 ng/mL | 120% |
| Maprotiline | Positive at 300 ng/mL | 100% |
| Nordoxepin | Positive at 700 ng/mL | 43% |
| Nortriptyline | Positive at 500 ng/mL | 60% |
| Perphenazine | Positive at 75,000 ng/mL | <1% |
| Prochlorperazine | Positive at 50,000 ng/mL | <1% |

| Tricyclic Antidepressant (TCA) *(Desipramine) 300 ng/mL*, continued | | |
|---|---|---|
| **Compound** | **Result** | **% Cross-Reactive** |
| Promazine | Positive at 900 ng/mL | 33% |
| Protriptyline | Positive at 50,000 ng/mL | <1% |
| Quetiapine (Seroquel) | Positive at 10,000 ng/mL | 3% |
| Trimipramine | Positive at 5,000 ng/mL | 6% |
| | | |
| Carbamazepine | Negative at 100,000 ng/mL | None Detected |
| Carbamazepine-10, 11 epoxide | Negative at 100,000 ng/mL | None Detected |
| Chlorpromazine | Negative at 100,000 ng/mL | None Detected |
| Clomipramine | Negative at 100,000 ng/mL | None Detected |
| Loxapine | Negative at 100,000 ng/mL | None Detected |
| Mirtazapine | Negative at 100,000 ng/mL | None Detected |
| Norclomipramine | Negative at 100,000 ng/mL | None Detected |
| Olanzapine | Negative at 100,000 ng/mL | None Detected |
| Phenothiazine | Negative at 100,000 ng/mL | None Detected |
| Thiothixene | Negative at 100,000 ng/mL | None Detected |

## Interference Data

**pH and Specific Gravity:**
The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was assayed with three negative clinical samples with pH values of 4.0, 7.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). All three pH samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was assayed with three samples with specific gravity values of 1.003, 1.015 and 1.030 ± 0.001. Each sample was assayed in triplicate. The specific gravity samples were fortified with drug concentrations as described above for pH to give strong negative and strong positive results. All three specific gravity samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

**Common Drugs:**
Drug free urine samples were spiked with drug concentrations that were the maximum level to give a strong negative (95% or greater negative) result (10-50% of cut-off, see Sensitivity data), and the minimum level above the cut-off to give a strong positive (95% or greater positive) result (125-150% of cut-off, see Sensitivity data). 100,000 ng/mL of the common drugs were then added to the preparation and assayed by the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System. If a common compound name is followed by the abbreviation "OXY", then it has cross-reactivity to the specified drug test (see "Related Compounds and Cross Reactants") and therefore was not assayed for interference for that drug test. Samples were evaluated in triplicate by in-house operators. None of the common drugs listed in Table 4 below affected the expected results.

**Table 4.**
**Common Drugs Evaluated with the MEDTOX*Scan*® Drugs of Abuse Test System**

| | | |
|---|---|---|
| Acetylsalicylic Acid | Chlorpheniramine | Morphine - **OXY** |
| Acetaminophen | Cocaine | Phenobarbital |
| Brompheniramine maleate | Dextromethorphan | Phenytoin (Diphenylhydantoin) |
| Caffeine | Doxylamine | d-Pseudoephedrine |
| Carbamazepine | Ibuprofen | Salicylic Acid |

**Discussion of Clinical Tests Performed for Determination of Substantial Equivalence:**

The accuracy of the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System was evaluated by assaying a panel of blind coded clinical urine samples containing varying concentrations of drugs and comparing to GC/MS or LC/MS/MS results. The samples were obtained from MEDTOX Laboratories and grouped in the following manner: Negative samples that screened negative by KIMS (Kinetic Interaction of Microparticles in Solution), and not confirmed by GC/MS or LC/MS/MS; Below Cutoff Negative samples that fell between limit of detection or quantitation and 50% of cutoff; Near Cutoff Negative samples that fell between 50% of the cutoff concentration and the cutoff concentration; Near Cutoff Positive samples that fell between the cutoff concentration and 150% of the cutoff concentration; and High Positive samples that were greater than 150% of cutoff concentration. Drug concentrations were assayed by GC/MS or LC/MS/MS. Concentrations used to assign the cutoff ranges for each drug were determined by summing the GC/MS or LC/MS/MS levels measured for all test-specific analytes found in the sample. The testing was performed by in-house operators. The results were interpreted at ten (10) minutes by the MEDTOX*Scan*® reader. No false positives were observed in the absence of drug. The results are summarized in Table 5 below.

**Table 5.**
**PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System**
**vs stratified GC/MS or LC/MS/MS Values**

| DRUG | P-V MEDTOX*Scan* Drugs of Abuse Test System | No Drug | Low negative by GC/MS or LC/MS/MS (Less than -50%) | Near Cutoff Negative (between -50% and cutoff) | Near Cutoff Positive (Between cutoff and +50%) | High Positive (greater than +50%) | % Agreement |
|---|---|---|---|---|---|---|---|
| **OXY (100)** | Positive | 0 | 0 | 0 | 3 | 36 | 98% |
| | Negative | 40 | 3 | 4 | 1 | 0 | 100% |
| **PPX (300)** | Positive | 0 | 0 | 4 | 4 | 40 | 100% |
| | Negative | 45 | 1 | 2 | 0 | 0 | 92% |
| **TCA (300)** | Positive | 0 | 0 | 3 | 4 | 36 | 100% |
| | Negative | 40 | 2 | 1 | 0 | 0 | 93% |
| **All Drugs** | Positive | 0 | 0 | 7 | 11 | 112 | 99.2% |
| | Negative | 125 | 6 | 7 | 1 | 0 | 95.2% |

For samples giving preliminary positive results below the cutoff and negative results above the cutoff, the assayed values are detailed in Table 6 below:

**Table 6.**

**ACCURACY/SUMMARY of DISCORDANT RESULTS**

| Drug and Cutoff Value (ng/mL) | P-V MEDTOX*Scan* Drugs of Abuse Test System | Drug or Metabolite GC/MS or LC/MS/MS Value (ng/mL) |
|---|---|---|
| OXY (100) | NEG | 102 |
| PPX (300) | POS | 182 |
| | POS | 194 |
| | POS | 228 |
| | POS | 271 |
| TCA (300) | POS | 194 |
| | POS | 217 |
| | POS | 287 |

**Conclusions:**

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System has the same intended use and similar technological characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new issues of safety or effectiveness. Thus, the PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Medtox Diagnostics, Inc.
c/o Mr. Phillip Hartzog
Director, R&D
1238 Anthony Road
Burlington, NC 27215

JUL 24 2009

Re: k091454
Trade Name: Profiles®-V MedtoxScan® Drugs of Abuse Test System
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Codes: DJG, JXN, LFI
Dated: May 15, 2009
Received: May 18, 2009

Dear Mr. Hartzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): k091454

Device Name: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System

Indications For Use:

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System consists of the PROFILE®-V MEDTOX*Scan*® Test Devices and the MEDTOX*Scan*® Reader. The PROFILE®-V MEDTOX *Scan*® Test Devices are one-step immunochromatographic tests for the rapid, qualitative detection of one or more of the following in human urine: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, THC (Cannabinoids), and Tricyclic Antidepressants or their metabolites. The PROFILE®-V MEDTOX*Scan*® Test Devices can only be used with the MEDTOX*Scan*® Reader. The MEDTOX *Scan*® Reader is an instrument used to interpret and report the results of the PROFILE®-V MEDTOX*Scan*® Test Device. PROFILE®-V MEDTOX*Scan*® Test Devices cannot be visually read.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System is for *in vitro* diagnostic use and is intended for professional use only. It is not intended for use in point-of-care settings.

The PROFILE®-V MEDTOX*Scan*® Drugs of Abuse Test System detects drug classes at the following cutoff concentrations:

| | | | | |
|---|---|---|---|---|
| AMP Amphetamine (d-Amphetamine) | 500 ng/mL | | OPI Opiates (Morphine) | 100 ng/mL |
| BAR Barbiturates (Butalbital) | 200 ng/mL | | OXY Oxycodone (Oxycodone) | 100 ng/mL |
| BZO Benzodiazepines (Nordiazepam) | 150 ng/mL | | PCP Phencyclidine (Phencyclidine) | 25 ng/mL |
| COC Cocaine (Benzoylecgonine) | 150 ng/mL | | PPX Propoxyphene (Norpropoxyphene) | 300 ng/mL |
| MAMP Methamphetamine (d-Methamphetamine) | 500 ng/mL | | THC Cannabinoids (11-nor-9-carboxy-r9-THC) | 50 ng/mL |
| MTD Methadone (Methadone) | 200 ng/mL | | TCA Tricyclic Antidepressants (Desipramine) | 300 ng/mL |

Configurations of the PROFILE®-V MEDTOX*Scan*® Test Devices may consist of any combination of the above listed and previously cleared drugs. Refer to specific product labeling for the combination of drug tests included on that test device.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k091454

The PROFILE®-V MEDTOX*Scan*® DRUGS OF ABUSE TEST SYSTEM PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROMETRY (GC/MS), HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) OR LIQUID CHROMATOGRAPHY / TANDEM MASS SPECTROMETRY (LC/MS/MS) ARE THE PREFERRED CONFIRMATORY METHODS. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE OBTAINED.

The MEDTOX*Scan*® Reader includes a Positive QC Test Device, a Negative QC Test Device and a Cleaning Cassette. The MEDTOX*Scan* ® Positive and Negative QC Test Devices are intended to detect errors associated with the MEDTOX*Scan*® Reader and a contaminated contact imaging sensor (CIS), and to verify that the CIS cleaning procedure using the MEDTOX*Scan*® Cleaning Cassette effectively removed any contamination.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Device Evaluation and Safety

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